

Applicant: Jeannette Whitcomb
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Please add new claims ~~32-38~~⁷³⁻⁷⁹ under the provisions of 37 CFR \$1.121 (c). New claims ~~32-38~~⁷³⁻⁷⁹ are presented in clean form with the entire set of pending claims attached as **Exhibit A** to be entered with applicant's Response.

Support for the amendment can be found, inter alia, within the specification for:

claim ~~32~~⁷³, on page 17, lines 17-20, page 46, lines 3-13;
claim ~~33~~⁷⁴, on page 18, line 35 to page 19, line 16; page 47, lines 13-20;
claim ~~34~~⁷⁵, on page 18, line 35 to page 19, line 16; page 47, lines 13-20; page 60, lines 5-8;
claim ~~35~~⁷⁶, on page 18, line 35 to page 19, line 16; page 37, lines 4-31;
claim ~~36~~⁷⁷, on page 18, line 35 to page 19, line 16; page 37, lines 4-31; page 60, lines 5-8;
claim ~~37~~⁷⁸, on page 57, lines 12-16; and
claim ~~38~~⁷⁹, on page 57, lines 12-14.

REMARKS

Claims 1-9, 17, 20, 23-31 are pending in the application. By this Amendment the applicant has added new claims 32-38 which were previously canceled by applicant's Preliminary Amendment filed with the application. Accordingly, claims 1-9, 17, 20, 23-31, and ~~32-38~~⁷³⁻⁷⁹ will be under examination.

In the October 2, 2000 Restriction Requirement, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I and

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II:

- I. Group I, claims 1-9 and 23-31, drawn to methods of assessing the effectiveness of non-nucleoside reverse transcriptase inhibitor (NNRTI) therapy in the HIV-infected patient, classified in class 435, subclass 5.
- II. Group II, claim(s) 17 and 20, drawn to a vector comprising a patient-derived segment, classified in class 435, subclass 320.1.

In addition, for Group I, the Examiner required election of a single specie from the following four species:

- a. Claims(s) 1-5, drawn to the detection of HIV RT mutants comprising a mutation at codon 236.
- b. Claims(s) 6-9, drawn to the detection of HIV RT mutants comprising a mutation at codon 225.
- c. Claims(s) 23-27, drawn to the detection of HIV RT mutants comprising a mutation at codon 230.
- d. Claims(s) 28-31, drawn to the detection of HIV RT mutants comprising a mutation at codon 181.

The Examiner alleged that the above groupings for the invention are distinct from each other for the following reasons:

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The Examiner stated that Groups I and II are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (citing M.P.E.P. 806.04 and 808.01). The Examiner alleged that the methodology of Group I neither requires nor uses the product of Group II. The Examiner further alleged that the product of Group II can be employed in a variety of different methodologies (i.e., recombinant protein production). Therefore, the Examiner alleged that each invention is drawn toward a different inventive entity.

The Examiner stated that because these inventions are allegedly distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The Examiner further alleged that the aforementioned species of Group I are directed toward the detection of disparate genotypic differences in the HIV genome and will each require independent searches.

In response, applicants hereby elect, with traverse, the claims of Group I, specifically claims 23-27, drawn to the detection of HIV RT mutants comprising a mutation at codon 230.

Applicant, however, respectfully requests that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

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Initially, the applicant respectfully requests that at least claims 28, 29, and 32-38 should be rejoined and examined with the elected method claims. Once the Examiner examines and finds patentable the elected claims of Group I, there would be no serious additional burden to examine 28, 29, and ~~32-38~~⁷³⁻⁷⁹ because claim 25 of elected Group II and claims 28, 29, 32, 35, 36, and 38 each share a common mutation at codon 181 and claim 23 of elected Group II and claims 33, 34, and 37 each share a common mutation at codon 230. Therefore the applicant submits that a search directed to the claims of elected Group II would be coextensive for a search of least claims 28, 29, and 32-38.

Furthermore, the applicant submits that the inventions of the cited Groups are not independent. First, under MPEP §802.01, "independent" means that there is no disclosed relationship between the subjects disclosed. However, the subject application clearly identifies the claimed methods (genotypic) and resistance test vectors (phenotypic) as drawn to assessing the effectiveness of non-nucleoside reverse transcriptase inhibitor HIV therapy (see, inter alia, page 1, lines 25-34 and page 7, lines 30-38). The Examiner alleged that the methods of Group I and resistance test vectors of Group II are not disclosed as capable of use together, or they have different modes of operation, or functions, or they have different effects. However, the applicant respectfully points out that the specification, inter alia, on page 67, lines 5-29, page 68, lines 32-35 and page 69 lines 1-5 clearly indicates that the subject resistance test vectors having the claimed mutations were used to establish a correlation between phenotypic susceptibility and genotypic analysis which forms the basis of the applicants' invention. The fact that the resistance test vectors

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having the claimed mutations were used to establish a correlation between phenotypic susceptibility and genotypic analysis clearly discloses that each are capable of use together, because in fact they were used in conjunction with one another to establish such a correlation for the specific claimed mutations and their effect on the effectiveness of particular NNRTI antiretroviral agents in HIV therapy. Clearly, the "mode of operation" and "function" of each are linked by the presence and effect of the claimed mutations to assess the effectiveness of NNRTI HIV therapy.

Indeed, it is the applicant's novel use of the claimed resistance test vectors having the specific claimed mutations which allow for the initial assessment of the effectiveness of particular NNRTI antiretroviral agents used in HIV therapy to establish a correlation that forms the basis for the claimed methods of the invention. Therefore, the applicant submits that there is no clearer case where the inventions of each Group are capable of use together, or share the same mode of operation (i.e., presence of a mutation affecting susceptibility to NNRTI agents) or the same function or effect (i.e., decrease/increase in susceptibility to particular NNRT agents due to the claimed mutations). Consequently, the applicant submits that the restriction requirement be withdrawn. Furthermore, the applicant has added new claims 37 and 38 to a resistance test vector having mutations at codons 230 and 181, which are the same mutations recited in the applicant's elected claims 23-27 of Group II.

Second, under MPEP § 803, there are two criteria for a proper restriction requirement: 1) the invention must be independent or distinct, and 2) there must be a serious burden on the Examiner if

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restriction is required. MPEP § 803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions."

Applicant respectfully submits that there would not be a serious burden on the Examiner if restriction is not required because a search of the prior art relevant to any of the claims of Group I would necessarily turn up the prior art relevant to the two claims contained in Group II, including new claims 37 and 38. Of further support to applicant's position is that the claims in Groups I and II, including new claims 37 and 38 share a common classification in the same class, namely class 435. Furthermore, the applicant respectfully requests that the Examiner examine all species within elected Group I, including new claims 32-36, because all of the claims in Group I, including applicant's new claims of 32-36, share a common classification in the same class 435, and same subclass, namely subclass 5. Therefore, since there is no serious burden on the Examiner to examine Groups I and II, together in the subject application, or all of the species within elected Group I, including new claims 32-38, it is submitted that the Examiner must examine all of the pending claims of the entire application on the merits.

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SUMMARY

In view of the foregoing, the applicant maintains that the October 2, 2000 restriction requirement is not proper under 35 U.S.C. § 121 and respectfully requests that the Examiner reconsider and withdraw the requirement.

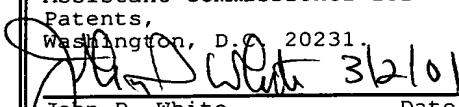
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

A check in the amount of \$878.00 is enclosed to cover the \$695.00 fee for a four-month extension of time and the \$183.00 fee for additional claims. If any other fee is required in connection with this Amendment, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: if
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John P. White Date
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